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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,208

07/16/2006

Mark Feldschuh

7784

60333

7590

07/23/2008

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EXAMINER

SIMMONS, CHRIS E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

07/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,208	Applicant(s) FELDSCHUH, MARK	
	Examiner CHRIS E. SIMMONS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/16/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the composition as set forth in claim 10 in the reply filed on 04/11/2008 is acknowledged.

Claim 12 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 04/11/2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 10, and 11 contain the trademark/trade name PLURONIC. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used

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properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyoxyethylene/polyoxypropylene copolymers gel and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0192288.

The reference teaches a composition of the invention comprising Poloxamer 407 (a specie of pluronic gel) and lidocaine. Examples of suitable flavoring agents include, but are not limited to, oil of spearmint, peppermint, and wintergreen (§ [0050]). Suitable preservatives include, but are not limited to, anti-microbial agents such as chlorhexidine (§ [0032]). Examples of suitable anti-oxidants include, but are not limited to, sodium bisulfite (§ [0045]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0192288 in view of USP 5,624,962 US 2003/0180352, and US 2004/0105885.

The disclosure of the primary reference is outlined above. The primary reference does not expressly teach sodium metabisulfite, phenylephrine, ethoxyl diglycol reagent, sodium metabisulfite, lecithin, or isopropyl palmitate/myristate.

The secondary reference discloses an aqueous drug composition having the property of reversible thermosetting gelation for ophthalmic, dermatological and body cavity (e.g., oral – col. 4, line 40) use which comprises effective amount, generally from

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about 0.001% to about 10% (col. 4, lines 57-58), of drugs (e.g., lidocaine – col. 4, line 52) used for pharmaceutical therapy or diagnosis, methylcellulose, 1.2 to 2.3 (W/V) % of citric acid (i.e., a flavoring) and 0.5 to 13 (W/V) % of polyethylene glycol (pluronic gel) (see col.2, lines 35-36), characterized in that said aqueous drug composition is fluid liquid before administration or application and forms gel at a body temperature of a local region immediately after administration or application (abstract). The composition may also comprise from about 0.001% to about 10% of phenylephrine HCl (col. 4, line 7), from about 0.001% to about 10% of chlorhexidine gluconate (col. 4, line 36), and from about 0.001 to 2% of preservatives, solubilizing agents (col. 4, lines 65-67), and surfactants (col. 5, lines 8-9). The reference does not expressly teach the composition as initially being in a gel form. The reference also does not expressly teach ethoxyl diglycol reagent, sodium metabisulfite, lecithin, or isopropyl palmitate/myristate.

The tertiary reference discloses that Transcutol (ethoxyl diglycol reagent) is a known solvent (§ 0220) and lecithin, isopropyl myristate, and isopropyl palmitate are known surfactants (§ 0211) used in oral compositions (§ 0272). The tertiary reference does not expressly teach each of the other ingredients recited in the claims in combination with the disclosed ingredients.

The quarternary reference discloses that ethoxydiglycol is a known pharmaceutical solvent (§ [0103]) and sodium metabisulfite is a known pharmaceutical antioxidant (i.e., a preservative) (§ [0117]). The quarternary reference does not expressly teach each of the other ingredients recited in the claims in combination with the disclosed ingredients.

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. Accordingly, it would have been obvious to add the ethoxyl diglycol reagent as the solubilizing agent, lecithin, isopropyl myristate, and isopropyl palmitate as the surfactants and sodium metabisulfite as the preservative to the composition of the primary reference because each of these ingredients are already known to be used in pharmaceutical compositions for these particular intended purposes (i.e., acting as surfactants, solvents, and preservatives).

As for claim 11, generally, it is not patentable to optimize the amounts of ingredients in a composition through routine experimentation. Differences in concentration from what is disclosed in the reference, will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is not inventive to discover the optimum or workable ranges by routine experimentation. *See MPEP 2144.05 [R-5] II A.*

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is

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(571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/
Examiner, Art Unit 1612

***/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612***